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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,858	07/21/2005	Bengt Herslof	C2432.0060	7315
32172	7590	11/16/2005	EXAMINER	
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 1177 AVENUE OF THE AMERICAS (6TH AVENUE) 41 ST FL. NEW YORK, NY 10036-2714			WALLENHORST, MAUREEN	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,858	<b>Applicant(s)</b> HERSLOF ET AL.	
	<b>Examiner</b> Maureen M. Wallenhorst	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8, 10, 11, 13-19, 22, 24-27, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10, 11, 13-19, 22, 24-27, 29 and 30 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 13 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/3/04</u> | 6) <input type="checkbox"/> Other: ____  |

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1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The declaration should not claim priority to application serial no. 10/516,858 under 35 USC 120 since this is not a previously filed application. Rather, application serial no. 10/516, 858 is the instant application. In addition, the filing date of application serial no. 10/516,858 is July 21, 2005, not December 3, 2004.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprises" and "comprising". Correction is required. See MPEP § 608.01(b).

5. Claims 10-11 and 13-14 are objected to because of the following informalities: In claim 10, the phrase "water and at least one mono-to trivalent alcohol is present" should be changed to --wherein water and at least one mono-to trivalent alcohol is present--. On line 2 of claim 11, the phrase "is selected from the group" should be changed to --selected from the group--so as to make proper sense. On line 2 of claim 14, the phrase "polar lipid lipid is a phospholipid" does not make proper sense. Appropriate correction is required.

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6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4, 10-11, 13, 15-19, 22, 24-27 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polar lipids such as glycolipids and phospholipids and non-polar lipids such as glycerides (i.e. glycerol esters of fatty acids), does not reasonably provide enablement for all possible polar lipids and all possible non-polar lipids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The scope of claims 1-4, 10-11, 13, 15-19, 22, 24-27 and 29-30, as presently written, is broader than justified by the description given in the specification. The terms “polar lipids” and “non-polar lipids” refer to an extremely large number of possible compositions, which are not all supported by the specification as originally filed. As noted above, the instant specification only provides support for the polar lipids being a membrane lipid such as a glycolipid or a phospholipid, and for the nonpolar lipid being a glyceride (i.e. glycerol esters of fatty acids).
8. Claims 15-19, 22, 24-26 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 4 of claim 15, the phrase “said components” lacks antecedent basis. On line 5 of claim 15, the phrase “the liquid continuous lipid phase” lacks antecedent basis. On line 7 of claim 15, the phrase “the solution of heparin” lacks antecedent basis.

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Claims 17-19 are indefinite since these claims depend from independent claim 15 but yet recite that the cooled solution is made into a powdorous product or a tablet. However, independent claim 15 already recites that the cooled solution is formed into a tablet. Therefore, the recitation of the formation of a powdorous product in claims 17-18 is not consistent with what is recited in claim 15, and the recitation of the formation of a tablet in claim 19 is redundant with what is recited in claim 15.

On line 2 of claim 26, the phrase “the continuous lipid phase” lacks antecedent basis.

Claim 29 is indefinite since it is not clear to whom the tablet is administered. On line 3 of claim 29, the phrase “characterized in that” is indefinite since it does not conform to standard US claim terminology. It is suggested to use the transitional term “wherein”.

On line 2 of claim 30, it is suggested to change the phrase “member of the group consisting of” to “member selected from the group consisting of”—so as to use proper Markush language.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-2, 4-6, 8, 10-11, 14 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Herslof et al (US Patent no. 5,665,379).

Herslof et al teach of a composition comprising a lipid matrix in combination with a bioactive material. The lipid matrix contains at least one polar lipid and at least one non-polar lipid. The polar lipid is preferably a membrane lipid such as phosphatidylcholine, and the non-polar lipid is preferably chosen from the classes of mono-, di- and tri- glycerides or a mixture thereof. See lines 14-34 in column 4 of Herslof et al. The lipid matrix also contains therein a bioactive material such as a drug, a herbicide, a food or a cosmetic ingredient. See lines 35-50 in column 4 of Herslof et al. The composition also can contain water, ethanol or other solvents in small amounts. See lines 49-52 in column 6 of Herslof et al. In addition, derivatives of lipids such as polyethylene glycol can also be included in the composition. See lines 20-27 in column 6 of Herslof et al. Herslof et al teach that the lipid matrix composition containing a bioactive material can be used as a pharmaceutical composition in the form of oral tablets. See lines 51-59 in column 4 of Herslof et al. The bioactive material can be fragmented heparin known as Fragmin<sup>TM</sup>. See lines 49-54 in column 7 and examples 12-15 of Herslof et al.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herslof et al. For a teaching of Herslof et al, see previous paragraphs in this Office action.

Herslof et al fails to teach what amount of water to include in the lipid matrix composition. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to adjust the amount of the water in the lipid matrix composition taught by Herslof et al to the levels recited in instant claims 3 and 13 since concentration is a result effective parameter that can be experimentally adjusted so as to optimize a particular procedure performed with a composition or a particular use of a composition.

15. Claims 1-6, 8, 10-11, 13-19, 22, 24-27 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nyqvist et al (US Patent no. 5,626,869, submitted in the Information Disclosure Statement (IDS) filed on December 3, 2004) in view of Rosenberg et al (WO 01/91729, also submitted in the IDS filed on December 3, 2004, English language equivalent being US 2003/0161884).

Nyqvist et al teach of a pharmaceutical composition containing a lipid system of at least two lipid components, wherein one of the lipid components is polar and the other is non-polar. The pharmaceutically active compound in the composition is heparin or a fragment thereof (i.e.

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Fragmin<sup>TM</sup>). A water containing solvent is also included in such an amount that discrete lipid particles are present. An alcohol such as ethanol can also be included in the composition. See example 4 in Nyqvist et al. The polar lipid can include phospholipids such as phosphatidylcholine or glycolipids. Non-polar lipids include mono-, di- or triglycerides. The glycerides have a preferred carbon chain length of between 6 and 12 carbon atoms. The composition can be used for oral administration. See the abstract, columns 1-2, lines 1-32 in column 3, lines 15-37 in column 4, lines 8-21 in column 6 and examples 1-7 in Nyqvist et al. Nyqvist et al fail to teach that the pharmaceutical composition can be in a tablet form.

Rosenberg et al teach of a solid composition containing heparin, a lipid component and a polymer. The lipid component constitutes mono-, di- or triglycerides having unsaturated fatty acid esters where the fatty acids have 8-18 carbon atoms. Preferred polymers include polyvinyl pyrrolidone and cellulose derivatives. The composition can be formed as powdered particles, capsules, pellets, tablets or preferably tablets with an outer coating of excipients. The composition is prepared by melt extrusion at 80-100 degrees Celsius, cooling and then forming a powder, capsule or tablet by grinding, compression, casting, injection molding, tableting under pressure or tableting under pressure with heat. Water or alcohol can be used as a solvent. See the abstract and paragraph nos. 0024, 0026, 0034, 0056-0057, 0067, 0100-0112, and 0122-0126 in Rosenberg et al (US 2003/0161884). Rosenberg et al also teach that the pharmaceutical composition can be used for the oral administration of heparin or a fragment thereof to a patient who has a condition such as thrombosis, pulmonary embolism, myocardial infarction, stroke and cardiovascular disorders. See paragraph nos. 0138 and 0141-0142 of Rosenberg et al.



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Based upon the combination of Nyqvist et al and Rosenberg et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to formulate the pharmaceutical composition containing a polar lipid, a non-polar lipid and heparin taught by Nyqvist et al into a tablet form using one of the common tablet production procedures disclosed by Rosenberg et al since Rosenberg et al teach that it is known in the art to administer heparin to patients in need thereof in a pharmaceutical tablet form, wherein the tablet contains therein heparin and a lipid component that serves to enhance the biological absorption and solubilization of heparin into a patient's bloodstream. It also would have been obvious to one of ordinary skill in the art to adjust the amounts of the various components in the pharmaceutical composition taught by Nyqvist et al to the amounts as recited in the instant claims since concentration is a result effective parameter that can be experimentally adjusted so as to optimize a particular procedure performed with a composition or a particular use of a composition.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Fischer et al (WO 01/66086), Ajani et al (US 2005/0020539 whose filing date is after the effective filing date of the instant application), Herslof (WO 03/068267, whose publication date and filing date are after the effective filing date of the instant application), Carlsson et al and US Patent no. 1,117,649, which teach of pharmaceutical compositions containing heparin or lipid components.

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

November 14, 2005

*Maureen M. Wallenhorst*  
MAUREEN M. WALLENHORST  
PRIMARY EXAMINER  
GROUP 400 1700